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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,493	03/01/2000	Maureen J. Charron	96700/613	3363

7590 11/26/2003

Craig J. Arnold eSQ
Amster Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER	
KAUSHAL, SUMESH	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/516,493	CHARRON ET AL.	
	Examin r	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

--Th MAILING DATE of this communication appears on the cover she t with th correspondence address --

THE REPLY FILED 04 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *73-79,92-94,98-100,104-106 and 110-112*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:
Claims 73-79, 92-94, 98-100, 104-106 and 110-112 stand rejected under 35 USC 101 regarding lack of specific and substantial asserted utility or well established utility and under 35 USC 112(1) regarding enablement issues for the same reasons of record as set forth in the office action mailed on 08/12/03.
Applicant argues that the published US2002/0038464 A1 of US Pat. App. Ser. No. 09/886,954, which is continuation in part of instant application indicates that the invention is useful in the diagnosis, treatment and monitoring of cancer. Applicant argues that the paragraph 0119, 0146-0151 and fig 1-2 in the published application reveled such finding.
However, this is found NOT persuasive because MPEP 2107 clearly states that the specification need to provide evidence that invention as claimed has specific, substantial and well-established utility a the "at the time of filing" and not after the date of filing when some one discover it. Even though applicant argument that '954 indicates that the invention is useful in the diagnosis, treatment and monitoring of cancer has been considered. Paragraphs 0119, 0146-0151 and fig 1-2 of the,'954 does not provide any evidence that instant invention has any specific and substantial asserted utility or a well established utility which enable one skill in the art to exercise the invention as claimed with any undue amount of experimentation. Paragraph 0119 of '954 only disclosed the detection of GLUTx protein in cardiac and tumor cells lysates using a GLUTx antibody. Furthermore, the fig-1 of '954 only compared the level of GLUTx protein with in tumor cells expressing neu, myc and ras oncogenes, and fails to provide any evidence that such a comparison could be used in the detection of a mammary tumor. In addition, 2-3 folds up-regulation of the claimed nucleic acid sequences in the liver of diabetic and hypoglycemic animal is not tissue-specific, since the instant specification clearly discloses the expression of GLUTX mRNA in variety of tissues includin brain, liver and testis of both normal and diabetic rats (instant spec. page 39). Furthermore, considering the applicant's disclosure it is even unclear that there are any differences in the GLUTX in the liver of diabetic and hypoglycemic animals. The data presented in the instant specification even fails to support applicant's assertion (see fig-8). Fig-8 discloses a very low expression of GLUTX mRNA transcripts in the liver of both normal and diabetic animals. In addition use of GLUTX antibodies to diagnose the breast cancer is not specific, since GLUTX protein is not limited to breast cancer tissue. GLUTX has also been found to express in testis, heart fat, liver, diaphragm and soleus muscles in both GLUT4 null and wild type mice (spec. page 39). In addition GLUTX has also been known to express in both brown and white adipose tissue (see fig-2). Since the breast tissues mainly comprises of adipose tissue, it is unclear how one skill in the art would specifically diagnose a breast cancer tissue form a non-cancerous form based upon GLUTX expression in breas tissue biopsy. Therefore, specification fails to provide any credible evidence, which establishes that over expression of GLUTX protein is the maker for the diagnosis of breast cancer or diabetes explicitly or implicitly as putatively considered by the applicant.

JEFFREY FREDMAN
PRIMARY EXAMINER